

Appl. No. 09/615,736  
Reply to Office Action of October 21, 2003

Attorney Docket: P65773US0

### REMARKS

The Office action mailed October 21, 2003, has been received and its contents carefully noted. The pending claims, Claims 16-19, 21-39, 42 and 44-48, were rejected. By this amendment, Claims 16, 22-26, 37, 39 and 46 have been amended to overcome the rejections. Claims 21, 27-36, 42, 44-45 and 47-48 have been cancelled, without prejudice and disclaimer. It is respectfully submitted that no new matter has been introduced by the amended claims. Support may be found in the specification and claims as originally filed. Reconsideration and entry of the amendment are respectfully requested.

#### **Rejections Under 35 U.S.C. §103**

Claims 16-19, 21, 23-34, 37-39, 42 and 44-47 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Haglund et al. (Nutritional Research, Vol. 13, pages 1351-1365, 1993), hereinafter Haglund. Claims 16-19, 21-39, 42 and 44-48 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over den Heijer et al. (Arterioscler. Thromb. Vasc. Biol. Vol. 18, 1998, pages 356-361) in combination with Horrobin (Prostaglandins Leukotr. Essential Fatty Acids, Vol. 53, 1995, pages 385-396) and Haglund.

Applicant traverses the rejection. It is respectfully submitted that in view of the presently claimed invention, the rejection has been overcome. At first, Claims 21, 27-36, 42, 44-45 and 47-48 have been cancelled, without prejudice and disclaimer. Therefore, rejection of Claims 21, 27-36, 42, 44-45 and 47-48 is moot. Secondly, Claim 16 has been amended to "formulation consisting essentially of eicosapentaenoic acid (EPA) or derivative; vitamin B12;

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folic acid, at a maximum daily dose of 5 mg; and vitamin B6, at a maximum daily dose of 20 mg; and, optionally, at least one antioxidant." As admitted by the Examiner, Haglund does not disclose the use of B-12. Therefore, the embodiment of the invention as defined in claim 16 is clearly distinguishable from Haglund. In addition, although Haglund discloses fish oils, this is not EPA alone. Fish oil is a mixture of different essential fatty acids. There is no disclosure in Horrobin that EPA should be taken without other essential fatty acids. Although Horrobin discloses the use of EFAs for treatment of vascular disease, linoleic acid, AA and DHA are singled out as the most important EFAs. It does not disclose EPA in combination with "vitamin B12; folic acid, at a maximum daily dose of 5 mg; and vitamin B6, at a maximum daily dose of 20 mg; and, optionally, at least one antioxidant." Den Heijer discloses that using vitamin B6, B12 or folic acid to lower homocysteine is desirable. However, it does not disclose these elements in combination with EPA.

Therefore, Haglund does not provide motivation and suggestion to combine with Horrobin and den Heijer to achieve the present invention, in which the specific ingredient and dose requirements are significantly different from prior art and lacking in prior art. Therefore, even if these references combined, they do not disclose the present invention. The "obvious to try" synergism in Horrobin is not sufficient to support the "obviousness" standard as required by 35 U.S.C. §103. In addition, rejection to Claims 17 – 19, 22 – 26, 37 – 39 and 46 is overcome by their dependency on Claim 16. It is respectfully submitted that the 35 U.S.C. §103 rejection be withdrawn.

Therefore, the invention as claimed is novel and nonobvious and the rejections under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) should properly be withdrawn.

Appl. No. 09/615,736  
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### Extension of Time

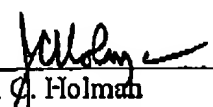
A Petition for Extension of Time for three month under 37 C.F.R. §1.136 and the appropriate fee has been filed to extend the due date for responding to the Official Action of October 21, 2003.

### Conclusion

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,  
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